IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, *Plaintiffs*, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, *Defendants*.	Civil Action No.: 19-12107 (KM)(JBC) Motion Return Date: TBD Oral Argument Requested *Document electronically filed*

PLAINTIFF-RELATOR ZACHARY SILBERSHER'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS (DKT. 128)

LITE DEPALMA GREENBERG & AFANADOR, LLC
Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

Attorneys for Plaintiff-Relator Zachary Silbersher

[Additional Counsel on Signature Page]

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

Other

INTRODUCTION

Plaintiff Zachary Silbersher's Second Amended Complaint (Dkt. 63) alleges that Defendants committed fraud to cause the United States and Plaintiff States to pay hundreds of millions of dollars more for the prostate cancer drug Zytiga (abiraterone acetate) than they should have.[1] Defendants are thus liable under the False Claims Act ("FCA"), 31 U.S.C. § 3729. Indeed, in what Defendants have described as a "nearly identical FCA action[]" (Dkt. 79-1 at 1 & n.2), the court recently denied a motion to dismiss, rejecting many of the same arguments Defendants raise here. *Silbersher v. Allergan Inc.*, __ F. Supp. 3d __, 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020), *appeal pending* No. 21-15420 (9th Cir. Mar. 9, 2021). This Court should do the same.

BACKGROUND

The key facts, which must be taken as true, are:

First, U.S. Patent 8,822,438 ("the '438 patent"), which claims the "invention" of co-administering abiraterone in combination with prednisone, is invalid because it was obvious to people of ordinary skill that abiraterone can be co-administered with prednisone. ¶¶ 68, 75-76, 78, 101-103. Accordingly, the patent application should have been rejected by the Patent Office—and for years, it repeatedly was rejected, until Defendants committed fraud. ¶¶ 75-81.

Second, on June 4, 2013, to overcome the sixth rejection of its patent application, Defendant Johnson & Johnson falsely represented to the Patent Office that Zytiga's purported commercial success in obtaining market share was attributable to the claimed invention of co-administering abiraterone with prednisone—a so-called "secondary consideration" that enabled Defendants to overcome the obviousness objection. ¶¶ 64-66, 82-83. This was false because J&J misrepresented Zytiga's performance and failed to disclose that Zytiga's purported commercial success was not attributable to co-administration with prednisone, but to other factors that J&J omitted. ¶¶ 84, 87.

Most glaringly, Defendants falsely claimed that Zytiga had gained significant market share

[1] References to the "Complaint" are to the Second Amended Complaint; Complaint citations are by paragraph number. Undefined capitalized terms have the meaning assigned in the Complaint. Citations to Defendants' memorandum of law (Dkt 128-1) are to "MTD." Other documents are cited by docket and page number.

in the market for chemo-naïve patients (patients who have not received chemotherapy) against its competitors from December 2012 (when Zytiga was FDA-approved for chemo-naïve patients) to April 2013. ¶¶ 82-84. But Defendants omitted that the drug Xtandi—Zytiga's principal competitor, and one of the competitors Defendants compared Zytiga to—was not FDA-approved for the chemo-naïve market at the time. ¶ 84(a). It was this lack of FDA approval, and not any advantage from the claimed invention, that largely explained Zytiga's success over Xtandi in this time period. Defendants knew this omission was important: In the same submission, Defendants justified Zytiga's low market share for a certain indication by emphasizing that Zytiga had not been FDA-approved for that indication during the relevant time period. ¶ 84(b)-(d).

The Complaint alleges numerous other material facts relating to commercial success that Defendants should have disclosed to the Patent Office, but did not. ¶¶ 84, 87. For example, Defendants failed to disclose that Zytiga's commercial success resulted from a blocking patent, which expired in December 2016. ¶¶ 8, 62, 87(e). They also did not disclose other factors that likely explained Zytiga's increased market share, *e.g.*, Zytiga's efficacy, safety, affordability, and ease of use compared to its competitors. ¶¶ 84(f), 87(c), (d), (g), (h). They did not disclose aspects of prostate cancer that contributed to Zytiga's market success. ¶ 87(b). And they manipulated the presentation by including data about Zytiga sales that did not include co-administration with prednisone, and by using a misleading definition of "market share." ¶¶ 84(e), 87(i).

Third, Defendants' June 4, 2013 submission misled the Patent Office into issuing the '438 Patent. ¶¶ 85-86, 88-90. But for Defendants' misrepresentations and material omissions, the Patent Office would have again rejected the application as obvious, and the patent monopoly protecting Zytiga would have ended by December 2016, when the blocking patent expired. ¶¶ 88-90, 93.

Fourth, generic manufacturers have been ready to enter the market since December 2016, but they were prevented from doing so by Defendants' fraudulent scheme. ¶¶ 92-105. After obtaining the '438 Patent, Defendants listed it in the FDA's Orange Book. ¶ 92. This forced generic manufacturers to submit so-called Paragraph IV certifications, stating that the listed patent is invalid or will not be infringed. ¶¶ 48, 50, 98. That allowed Defendants immediately to sue for

infringement—and by statute, the initiation of such litigation delays FDA approval of the generic for at least 30 months. ¶ 51. Defendants used this procedure to assert the '438 Patent in several objectively baseless infringement actions, preventing generic manufacturers from entering the market. ¶ 99. This was unlawful because Defendants were required to list only those patents that "could reasonably be asserted" against generic competitors. *See* 21 U.S.C. § 355(b)(1)(A)(viii). Defendants knew the '438 Patent was invalid but listed it to block competitors. ¶¶ 58, 97-100.

Fifth, Defendants' conduct unlawfully propped up the market price of Zytiga. The entry of generic competitors would have caused Zytiga's price to drop by at least 85%, and Defendants would have lost 90% of Zytiga's market share. ¶¶ 8, 55.

Sixth, Defendants used the tainted market price to manipulate the prices the Government paid for Zytiga. Indeed, because Zytiga's patient population is elderly, government programs pay for 80% of U.S. Zytiga prescriptions. ¶ 6. As part of the process of obtaining eligibility for reimbursement under various Federal programs, Defendants submitted Zytiga for listing on the Federal Supply Schedule ("FSS"). ¶ 112. In that process, Defendants submitted the market prices for Zytiga to the Government, which was required to ensure the Government paid a "fair and reasonable" price for Zytiga. *See* 48 C.F.R. §§ 8.404(d); 15.402(a) (2018). Defendants knew the price of Zytiga had been inflated by fraud, yet they submitted those inflated prices to mislead the Government into paying a higher price for Zytiga than was fair and reasonable. ¶¶ 110, 117.

Seventh, Defendants' conduct harmed the Government, which favors less expensive generic drugs. By unlawfully excluding generic competitors from the market, Defendants denied the Government that choice, causing the Government to pay money to Defendants that it otherwise would not have. ¶¶ 108-109. Defendants' fraudulent scheme also resulted in the Government paying or reimbursing inflated monopoly prices. ¶¶ 36, 108-09, 124-25, 112, 115, 132.

ARGUMENT

The FCA is the principal civil remedy for fraud on the Government. The statute imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a

false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). A "claim," is "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that" is "presented to an officer, employee, or agent of the United States," or "to a contractor, grantee, or other recipient, if the money or property is to be spent or used . . . to advance a Government program or interest." *Id*. § 3729(b)(2)(A). The statute is broad because Congress intended to "reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003).

The FCA allows any private person to sue on the Government's behalf. *See* 31 U.S.C. § 3730(b). Such plaintiffs are known as *qui tam* relators. Sometimes they are insiders, or even participants in the fraud. Other times, they are knowledgeable outsiders who use their education, experience, or talent to uncover a fraudulent scheme. Congress wanted all these people to sue under the FCA, because "only a coordinated effort of both the Government and the citizenry will decrease [the ongoing] wave of defrauding public funds." S. Rep. No. 99-345, at 2 (1986).

The Complaint in this case states heartland violations of the FCA, and Defendants' arguments for dismissal lack merit. This brief addresses the arguments in the order Defendants made them.

I. Defendants Are Not Entitled to Dismissal on Public Disclosure Grounds

Defendants argue that even if they committed fraud, Silbersher's suit must be dismissed because the allegations or transactions alleged in the Complaint were publicly disclosed. MTD 7-23. The FCA's public disclosure bar is an affirmative defense, providing for dismissal:

> [I]f substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the

action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). If no qualifying public disclosure occurred, then the defense fails. Even if a qualifying disclosure occurred, however, the relator may proceed if he is an "original source," meaning that he has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and "has voluntarily provided the information to the Government before filing an action under this section." *Id*. § 3730(e)(4)(B).

The public disclosure bar was added to the FCA in 1986, in a suite of amendments designed to "encourage more private enforcement suits." S. Rep. No. 99-345, at 23-24. It replaced the "government knowledge bar," which barred any *qui tam* action based on information the Government already knew—because the government knowledge bar was too broad. *See* S. Rep. No. 110-507, at 5 (2008). "This new, public disclosure bar was designed to bar only truly parasitic cases," *i.e.*, cases "where a *qui tam* relator brought no new information to the Government," such as cases "brought by individuals who did nothing more than copy a criminal indictment filed by the Government." *Id*. at 5, 22.

Unfortunately, as the architects of the public disclosure bar noted, this provision, "which was drafted to deter so-called 'parasitic' cases, [had] been converted by several circuit courts into a powerful sword by which defendants are able to defeat worthy relators and their claims," in a manner that threatened to undermine "the very purpose" of the 1986 Amendments. 145 Cong. Rec. E1546-01 (daily ed. July 14, 1999), 1999 WL 495861, at *E1546 (Statement of Rep. Howard Berman & Sen. Charles Grassley). These legislators succeeded in amending the public disclosure bar to correct course in 2010. These changes "overhauled" and "radically changed" the FCA to "lower the bar for relators." *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 298-99 (3d Cir. 2016). Three changes matter here.

First, the prior version of the bar applied when a complaint was "based upon" publicly disclosed allegations or transactions. The 2010 amendments replaced "based upon" with "substantially the same." As the Sixth Circuit has explained, "[f]rom a textual standpoint, 'substantially the same' facially demands a greater degree of similarity between the *qui tam*

complaint and the prior disclosures than 'based upon' does. And 'substantially the same' undoubtedly is more rigorous than 'even partly based upon,' as we interpreted 'based upon' to mean." *United States ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836, 851 (6th Cir. 2020). Thus, under the statute as written today, it is not enough that some part of the relator's complaint was publicly disclosed. All of the essential elements must have been. *See ibid.*[2]

Second, the 2010 amendments narrowed the channels for triggering disclosures. The first channel previously covered *any* criminal, civil, or administrative hearing. The 2010 amendments narrowed it to encompass only "Federal criminal, civil, or administrative" hearings "in which the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A)(i). Thus, "information that was disclosed in a federal case between private parties no longer constitutes publicly disclosed information." *Moore*, 812 F.3d at 299. Moreover, the second channel previously applied to disclosures in any congressional, administrative, or Government Accountability Office report, hearing, audit, or investigation. As the Supreme Court noted, this was partially redundant with the first channel, which also included administrative hearings. *See Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 408 (2011). The 2010 amendments eliminated the redundancy by removing the word "administrative" from the second channel and adding the qualifier "Federal" (overruling judicial decisions holding that state and local reports and investigations could trigger the bar, *e.g., Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson,* 559 U.S. 280 (2010)), so that it now applies only to disclosures "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation." 31 U.S.C. § 3730(e)(4)(A)(ii). The amendment makes clear that the second channel does not apply to administrative hearings (which are now governed solely by the first channel).

Third, Congress expanded the definition of an "original source," *i.e.*, a relator who can

[2] Defendants cite *United States v. Omnicare, Inc.*, 903 F.3d 78, 83 n.6 (3d Cir. 2018), for the proposition that "substantially the same" means "based upon." MTD 8. The *Omnicare* court said, in *dictum*, that the 2010 amendment codified the circuit's prior interpretation of "based upon." But nobody in that case argued otherwise. To the extent the issue is relevant here, this Court should adopt the Sixth Circuit's holding that "substantially the same" is narrower than "based upon."

proceed even if the public disclosure bar has been triggered. The previous definition required "direct and independent knowledge of the information on which the allegations are based"—and courts interpreted that to require a relator to have firsthand knowledge of the historical facts underlying the fraud. The architects of the public disclosure bar believed this was wrong. They thought that "a relator who learns of false claims by gathering and comparing data could have direct and independent knowledge of the fraud, regardless of his or her status as a [percipient] witness," and that relators who use "their education, training, experience, or talent to uncover a fraudulent scheme from publicly available documents, should be allowed to file a *qui tam* action" 145 Cong. Rec. E1546-01, at *E1547. Congress codified that understanding in 2010, and a relator now needs only have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). The Third Circuit has also held that under the new definition, a relator may qualify by contributing "information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'" *Moore*, 812 F.3d at 307.

At bottom, this is not the sort of case that Congress wanted to bar. Here, the Government was not aware of the fraud, and Silbersher is helping recover money that the Government would not otherwise have recovered. Congress wanted to encourage that effort by the citizenry, not stifle it. The State of California recently said as much in a similar case, explaining that:

> Mr. Silbersher's suits are neither "parasitic" nor "opportunistic." We are not aware of any government agency that regularly monitors patent filings to determine whether there has been a material omission or misrepresentation in applications for pharmaceutical patents, particularly given the specialized expertise and amount of resources that would be required to do so. We therefore welcome the efforts of relators like Mr. Silbersher to help identify instances where drug patents are not just invalid, but fraudulent—particularly in a case like this, where there was apparently no pre-existing government investigation concerning the alleged fraud. Such efforts, if successful, may help lower the price of medicine and the cost of health insurance, which is consistent with our mission.

Statement of Interest on Behalf of the State of California, by and Through the Cal. Ins. Comm'r, *United States ex rel. Silbersher v. Allergan PLC*, No. 18-cv-03018-JCS, Dkt. 133, at 3 (N.D. Cal.

June 8, 2020) (footnote omitted). The district court found that no qualifying public disclosure had occurred, and that analysis persuasively shows why Defendants are wrong here. As set forth below, Defendants are not entitled to dismissal on public disclosure grounds.

A. Neither Silbersher's Allegations Nor the Underlying Fraudulent Transactions Were Publicly Disclosed

Defendants do not have a straight-faced argument that Silbersher's allegations of fraud were publicly disclosed before he filed his complaint. The allegations are detailed above. They include that Defendants: (1) lied to the Patent Office about the reasons for Zytiga's commercial success to obtain the '438 Patent; (2) improperly listed the '438 Patent in the Orange Book and then asserted it against generic competitors to block them from entering the market; (3) used the unlawfully inflated market price to increase the price the Government paid; and (4) reaped millions of extra dollars from Government payors as a result.

Defendants do not identify any public source that disclosed any of those essential allegations—let alone all of them, as required for the public disclosures to be "substantially the same" as the allegations in the complaint. Defendants argue that the IPR petitions filed against them included allegations of fraud on the Patent Office. MTD 9-11. But the petitions Defendants cite merely argued that Defendants' attempts to link the commercial success of Zytiga to the claimed invention were *insufficient*—not *fraudulent*. Moreover, the petitions did not make "substantially the same" allegations as Silbersher's complaint. For example, none of the IPRs alleges that Defendants omitted key facts from their submissions to the Patent Office, *e.g.*, ¶ 87(c)-(h) (facts about the administration and price of Zytiga).

Indeed, none of Defendants' disclosures reveal one of the most important allegations of fraud in the Complaint: Defendants' failure to disclose that Zytiga's principal competitor for chemo-naïve patients (Xtandi) had not obtained FDA approval for the chemo-naïve indication during the relevant time period when presenting a market share comparison between Zytiga and alternative

treatments. *Compare* ¶ 84(a)-(d) *with* Dkt. 128-5 Exs. D-F.[3] Defendants assert that the IPR petitions challenged Defendants' market share analysis as "deficient" or "misleading and incomplete . . . when viewed in the proper market context" MTD Appx. A, at 1, citing Dkt. 128-5, Exs. D & E; MTD 10, *citing* Dkt. 128-5, Ex. E, at 52 & 205. But none of the petitions ever discloses the key fact, *i.e.*, that Xtandi was not FDA-approved for chemo-naïve patients at the time. It certainly does not disclose that Defendants made a knowing misrepresentation about Xtandi—which is the key allegation in Silbersher's complaint. ¶ 84(a)-(c).

Defendants also claim this omitted fact was disclosed during prosecution of the '438 Patent. MTD 11-12. This is not a point about public disclosure at all; it is instead simply a false denial of the factual allegation that Defendants misled the Patent Office, and therefore inappropriate at the pleading stage. In any event, the sources Defendants cite do not exonerate them. Defendants point to a press release announcing Xtandi's approval for a completely different indication—for chemo-*refractory*, not for chemo-*naïve*. Dkt. 128-5, Ex. C; MTD App. A, at 1. Defendants also claim they "could not have disclosed Xtandi's not-yet-extant approval date for the chemo-naïve market." MTD 12. That argument is disingenuous. Even if Defendants could not have predicted the date Xtandi would receive approval for chemo-naïve patients, they could and should have told the Patent Office that Xtandi had not yet been approved for those patients. Instead, to acquire the '438 Patent, Defendants told the Patent Office that, by April 2013, Zytiga's market share was higher than Xtandi's for the chemo-naïve market, Dkt. 128-5, Ex. A at 38, 58, and used this fact to assert that the claimed invention had caused Zytiga to gain market share against its competitors. That was misleading, and Defendants' assertion that they disclosed everything they knew to be material and relevant to patentability is demonstrably false.

In any event, the fraud on the Patent Office was only the first step—and Defendants do not identify any public source alleging that Defendants wrongly asserted the '438 Patent against

[3] Defendants cite sources indicating when Xtandi was approved (*i.e.*, Dkt. 128-5 Exs. C, T, U QQ, PP, RR and PP), but that's all beside the point: Defendants failed to disclose the relevant approval dates when making their critical market share comparison, making the comparison misleading.

generic competitors, inflated the price they charged the Government, or submitted false claims for payment. They cannot say that "substantially the same" allegations were publicly disclosed by anybody else.

Because Silbersher's allegations were not disclosed, Defendants are left to argue that "substantially the same" "transactions" were publicly disclosed. For a "transaction" to be publicly disclosed, *both* the misrepresented state of facts, and the true state of affairs revealing the defendant's representation to be false or fraudulent, must be disclosed in an enumerated channel. *See Omnicare*, 903 F.3d at 84.

Defendants gesture at sources that they argue a person could scrutinize to infer some of the transactions alleged in the Complaint. But many of Defendants' misrepresentations were omissions, and therefore not disclosed. For example, to detect Defendants' misrepresentation vis-à-vis Xtandi, a person would have to know that Xtandi had not received FDA approval for chemo-naïve patients, review all of Defendants' submissions to the Patent Office, notice that Defendants had omitted that fact, and understand why the fact made Defendants' representations about commercial success misleading. In other words, a person would have had to discern two *missing* facts (that Xtandi did not have FDA approval for chemo-naïve patients, and that Defendants had failed to mention that non-approval) as well as their significance. Given how difficult it would have been for anybody to notice those twin missing facts, it is quite a reach to argue that Defendants' fraud was in the public domain, or to presume that the Government saw the fraud and chose not to pursue it.[4]

Defendants also fail to show how the other "transactions" underlying the Complaint, *e.g.*, their improper listing of the '438 Patent in the Orange Book, the improper use of the inflated market price to inflate the price the Government paid, and the actual false claims for payment, were publicly disclosed. For these facts, Defendants have not identified any public source disclosing the true state of affairs, *i.e.*, that the listing in the Orange Book was improper, that the

[4] Indeed, nobody before Relator seems to have pieced this together, though several generic companies previously challenged the patent.

market price of Zytiga was inflated by an unlawful patent monopoly, or that the Government was overpaying for drugs. They also have not cited any legal authority for the proposition that the potential public disclosure of one transaction in a complaint (*e.g.*, fraud in connection with the '438 Patent) automatically discloses all of the subsequent transactions underlying a complaint. In fact, the opposite is true. *See, e.g.*, *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 264 (E.D Pa. 2020) (explaining that Third Circuit precedent requires court to undertake a "particularized, fact-specific approach" when deciding whether a fraud has been publicly disclosed).

B. The Asserted Public Disclosures Did Not Occur in an Enumerated Channel

Even if Defendants showed that the allegations or transactions had been publicly disclosed, those disclosures did not occur in the enumerated statutory channels, and so cannot trigger the public disclosure bar. Defendants say that their false statements to the Patent Office were disclosed: (1) The IPR petitions, which defendants argue are papers submitted in "hearings" under the first and second channels; and (2) the patent prosecution histories, available through a website called Patent Application Information Retrieval ("PAIR")—similar to PACER for civil cases—which Defendants argue is a "Federal report." MTD 17-22. These arguments are wrong.

1. Congress Excluded IPRs and Patent Prosecution Dockets from the Public Disclosure Bar Through the 2010 Amendments

IPRs and patent prosecutions are administrative proceedings in which the Government is not typically "a party." One of the ways Congress "overhauled the public disclosure bar" in 2010 was to provide that "information that was disclosed in a criminal, civil, or administrative hearing now qualifies as a public disclosure only if the information was disclosed in a federal case to which the government was a party." *Moore*, 812 F.3d at 299. "When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 258-59 (2004); *see also Hayes v. Harvey*, 903 F.3d 32, 42 (3d Cir. 2018) (*en banc*) (similar). Applying that principle, the court in *Allergan* determined that neither IPRs nor patent prosecutions fall within the enumerated channels. 2020 WL 7319407, at *18-26. As that court explained, Congress in 2010 made a deliberate decision to limit the sorts of

Federal civil, criminal, and administrative hearings that could trigger the public disclosure bar to those in which the Government or its agent is a party. The public disclosure bar's enumerated channels should be read to give effect to that legislative intent—which means that channels (ii) and (iii) should not be read so broadly as to include materials from hearings that Congress specifically carved out of the statute when it narrowed channel (i).

Defendants concede that patent prosecutions are "*ex parte* agency proceedings," and are therefore expressly carved out from channel (i) because the Government is not a party to them. MTD 20. Nevertheless, Defendants argue that the PAIR website—which does nothing more than display filings submitted during patent prosecution—is a "Federal report" under channel (ii). MTD 20-21. To understand why this is wrong, it is important to understand how PAIR works. PAIR is the patent prosecution system's counterpart to the Federal courts' PACER system. It creates a docket sheet for each issued patent (called an Image File Wrapper), with hyperlinks to filings submitted during the application process. The wrappers are produced and updated automatically in real time. Such files are available for millions of patents. *See* USPTO, Patent Examination Research Dataset (Public PAIR) (last updated Aug. 19, 2020), https://www.uspto.gov/learning-and-resources/electronic-data-products/patent-examination-research-dataset-public-pair.
Defendants argue that this massive dataset of docket sheets is a "Federal report" because, they say, a "report" is anything "that gives information," or provides "an official or formal statement of facts or proceedings." MTD 20 (quoting *Schindler*, 563 U.S. at 407-08).

After the 2010 amendments, Defendants' interpretation is contrary to the case they cite, and other controlling precedents, too. In *Schindler*, the Supreme Court instructed that "to determine the meaning of one word in the public disclosure bar, we must consider the provision's entire text, read as an integrated whole." 563 U.S. at 408. Indeed, the Court emphasized that "*all* of the sources [of public disclosure] listed in § 3730(e)(4)(A) provide interpretive guidance" about each other. *Id*. at 409. *Schindler* itself was about the pre-amendment version of the statute, and the opinion makes clear that it related "to the statute as it existed when the suit was filed," and not to the amended statute. *Id*. at 404 n.1. Before the amendment, reading the word "report" to include civil

and administrative docket sheets may not have run afoul of *Schindler's* teaching to read the statute as an integrated whole, because every civil and administrative hearing already triggered the bar under channel (i), and so it would not matter whether the docket sheets for those hearings were also "reports" under channel (ii).

After the 2010 amendments, treating the docket sheets of hearings governed by channel (i) as "reports" under channel (ii) is untenable—because it would effectively undo Congress's deliberate attempt to narrow channel (i) by adding the Government-party requirement, impermissibly robbing the amendment of "real and substantial effect." *Hayes*, 903 F.3d at 42. Under Defendants' interpretation, everything on PACER would be a "Federal report" under channel (ii) because PACER "gives information" about Federal court cases, or provides an "official record" of those proceedings. Thus, even though Congress deliberately carved civil actions between private parties out of channel (i), every filing submitted in those cases would be swept back in under channel (ii). The upshot is that channel (i) would be rendered superfluous vis-à-vis civil actions, and Congress's intent in amending the statute would be undone. The same logic applies to patent prosecutions, which Defendants concede were carved out of channel (i) in 2010. As the court explained in *Allergan*, "considering as a whole the three subsections of the current version of the public disclosure bar, . . . the term 'Federal report' should not be construed so broadly as to encompass documents that are publicly available on PAIR," because to do so would "significantly undermine[]" the 2010 amendments. 2020 WL 7319407, at *20.

Accordingly, the correct reading is that if the asserted public disclosure occurs during a Federal "hearing" that is "criminal, civil, or administrative," then the bar *only* applies if "the Government or its agent is a party," as provided in channel (i). By contrast, channel (ii) covers "Federal . . . hearing[s]" to the extent they are *not* criminal, civil, or administrative in nature, *e.g.*, congressional hearings, which is the example Congress provided in (ii) itself.[5] But really, channel

[5] In arguing that channel (ii) embraces administrative hearings such as IPRs and patent prosecutions, Defendants rely on *ejusdem generis*, MTD 15-16. That canon, along with *noscitur a sociis*, cuts against them, because administrative hearings are not "the same kind" as Congressional hearings—and Congress specifically removed "administrative" in the 2010 amendments.

(ii) focuses mostly on things that aren't hearings, *i.e.*, reports, audits, and investigations. This interpretation gives meaning to every word in the statute, and is the only one consistent with the 2010 amendments, which narrowed the public disclosure bar by adding the Government-party limitation to channel (i), and removed the word "administrative" from channel (ii). This reading also implements the maxim "that the specific governs the general," *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012), by allowing the specific provision Congress enacted for Federal criminal, civil, and administrative hearings to take precedence over the more general provision for other Federal hearings. Under this interpretation, patent prosecution filings cannot trigger the bar unless the Government or its agent was the applicant for the patent, and therefore a "party" to the prosecution; in this case, it was not.

The same is true of IPRs, which Defendants argue are "hearings" under channels (i) and (ii). Defendants' argument is puzzling, because although they argue that IPRs are hearings under channel (i), they never explicitly argue that the Government is a party to IPRs, and they never cite any case so holding. MTD 17-18. This is in contrast to Defendants' earlier motion to dismiss, which explicitly argued (albeit without authority) that the Government was a party to IPRs. Dkt. 79-1, at 11. Now, Defendants beat around the bush, arguing that the Government plays a "substantive role," is "actively invested in the merits," and does "more than provide a neutral forum." MTD 17. But none of that makes the Government a "party"—and Defendants do not argue otherwise. On this basis alone, the Court could reject Defendants' channel (i) argument.

Even ignoring Defendants' failure to actually argue their point, the Court should hold that IPRs are not hearings in which the Government is a party. A "party" means one of the protagonists in a legal proceeding, *i.e.*, a person on one side or the other of the "v." in the caption. In general, the Government becomes a party by bringing a case, by having a case brought against it, or by intervening in a case. *See, e.g.*, *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009) (explaining that "intervention is the requisite method for a nonparty to become a party to a lawsuit"). Defendants accept that when the Government acts principally as an adjudicator, however, it is not a "party." MTD 16. Indeed, the Government is not a party to this FCA action

even though it is the real party in interest, stands to receive most of the recovery, and is endowed by the statute with certain rights (*e.g.*, the right to be served with documents)—because the Government has not intervened. *See Eisenstein*, 556 U.S. at 933.

The Supreme Court has also confirmed, twice, that the Government is not a party to most IPRs. Every IPR begins with a petition to institute review. Only a private person can petition; the Government is legally prohibited from doing so. *See Return Mail, Inc. v. United States Postal Serv.*, 139 S. Ct. 1853, 1866 (2019). Congress did not "authorize[] the Government . . . to become a party to a full-blown adversarial proceeding before the Patent Office and any subsequent appeal." *Ibid*. In *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Court also explained that "*a party* may seek inter partes review by filing 'a petition to institute an inter partes review.' § 311(a). This language doesn't authorize the Director [of the Patent Office] to start proceedings on his own initiative." *Id.* at 1355 (emphasis added). These binding precedents plainly distinguish between the parties to IPRs, on the one hand, and the Government, on the other. Defendants do not cite or discuss *SAS Institute*, but it is damning to their position.

Once the petition is filed, the Director decides whether to institute an IPR, *i.e.*, whether to allow the petitioner's claim to go forward on the merits. As the Supreme Court explained in *SAS Institute*, this decision is heavily circumscribed. The Director cannot "initiate whatever kind of inter partes review he might choose"; the Director has "a binary choice—either institute review or don't," on terms provided by the petitioner. *SAS Inst.*, 138 S. Ct. at 1355. Thus, it is "the petitioner's petition, not the Director's discretion," that "guide[s] the life of the litigation." *Id*. at 1356.

An institution decision is also, as a legal and practical matter, a judicial determination. By regulation, the Director has delegated institution decisions to the administrative judges of the PTAB. *See* 37 C.F.R. § 42.4(a). These judges apply the statutory criteria that IPR can be instituted if, based on the parties' initial filings, "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged." 35 U.S.C. § 314(a). Thus, at the institution stage, a panel of judges evaluates the strength of the parties' arguments and weeds out

weak cases—much like a court ruling on a motion to dismiss. That is adjudicator behavior, not litigant behavior, and so actually refutes the contention that the Government is a "party."[6]

The course of IPRs after institution further underscores that the Government is not a party. Once an IPR is instituted, the Government does not file papers, make arguments, examine witnesses, or engage in any other party-like behavior. Instead, as the Supreme Court has explained, "the petitioner's contentions, not the Director's discretion, define the scope of the litigation all the way from institution through to conclusion." *SAS Inst.*, 138 S. Ct. at 1357. Thus, the private parties (the petitioner and the patent owner) make adversarial presentations to the judges of the PTAB, who are required by statute to decide whether any of the challenged patent claims are invalid, and to issue a final written decision that resembles a judicial opinion. *See* 35 U.S.C. § 318(a).[7]

Against all this, Defendants stress that the Director makes institution decisions, citing Federal Circuit cases describing IPRs as akin to enforcement actions. *See* MTD 17-18, *citing Regents of Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1339 (Fed. Cir. 2019), and *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018). As explained above, the Director's role in institution decisions does not make the Government a party. Defendants' cases are unpersuasive because they are about a completely different matter: Whether state or tribal immunity defeats the PTAB's jurisdiction. Whatever else those cases say about the nature of IPRs, they never say that the Government is a "party" to them—and even if they did, that would have to be disregarded under the Supreme Court's binding decisions in *Return Mail* and *SAS Institute*.

---

[6] The judges may decide not to institute review even though the petitioner has a reasonable likelihood of prevailing. Thus, judges sometimes decline to institute IPR when the same petitioner has previously challenged the same patent, *see, e.g.*, *Gen. Plastic Indus. Co., Ltd. v. Kaisha*, 2017 WL 3917706, at *4 (P.T.A.B. Sept. 6, 2017), or if district court proceedings involving the same patent are far along, *see, e.g.*, *Apple Inc. v. Fintiv, Inc.*, 2020 WL 2126495, at *2 (P.T.A.B. Mar. 20, 2020). But that is no different from courts dismissing a case for discretionary prudential reasons—*e.g.*, abstention or *forum non conveniens*. The bottom line is that institution decisions are made by judges applying legal criteria; they are not analogous to a litigant's decision to sue.

[7] The administrative rules governing trials before the PTAB, codified at 37 C.F.R. Part 42, likewise distinguish between the "parties" to a proceeding, on the one hand, and the "Board," *i.e.*, the Government judges, on the other. For example, the definition of a "party" includes "the petitioner" and "the patent owner," but not the Board or the Government. 37 C.F.R. § 42.2.

Defendants also argue that if a petitioner stops participating in an IPR, "the PTAB may prosecute the IPR to decision, and the PTO can defend PTAB decisions on appeal." MTD 17. But the fact that the PTAB retains jurisdiction to decide abandoned IPRs doesn't make the Government a party, because even then the PTAB still acts only as an adjudicator. That the Director has "the right to intervene in an appeal," 35 U.S.C. § 143, actually supports Silbersher. We concede that if the Government intervenes on appeal, the Government becomes a party to the proceeding. On the other hand, the fact that the Government *has to* intervene shows that it was not a party in the first instance—because intervention is what nonparties do to join an action. *Cf. Eisenstein*, 556 U.S. at 933 ("[T]here would be no reason for the United States to intervene in an action in which it is already a party."). Thus, until the Government intervenes, it is not a party to the IPR.

No such intervention occurred here. The IPRs at issue in this case were conducted entirely by private parties. Thus, the captions list the parties—and the Government is not on either side of the "v." *See* Dkt. 128-5, at 66, 141, 219 (captions for Dkt. 128-5, Exs. D, E, F). The private parties did not abandon the IPRs prematurely, and so the PTAB judges were required to issue decisions. When those decisions went up on appeal (well after this case commenced), the Government was not a party there, either. *See BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1063 (Fed. Cir. 2019) (caption of appeal). Thus, the IPRs were proceedings between private parties—and as the Third Circuit has held, "information that was disclosed in a federal case between private parties no longer constitutes publicly disclosed information." *Moore*, 812 F.3d at 299.

The foregoing establishes that the IPRs in this case were not "hearings" under channel (i). Defendants also argue that IPRs constitute Federal "hearings" or "investigations" under channel (ii), and that decisions in IPRs are Federal "reports." MTD 18-19. To set this argument up, Defendants attempt to distinguish between "adversarial adjudicative proceedings," which they argue fall under channel (i); and "non-adjudicative, administrative activities wherein the Government plays an investigative or inquisitorial role," which they argue fall under channel (ii). *Id*. at 15-16. Then, after arguing that IPRs fall within channel (i), they do an about-face and argue that they also fall under channel (ii), because an IPR is "an inquisitorial proceeding in the United

States' sovereign capacity to aid its administration of patent-related laws and policy." *Id*. at 18. Defendants also cite *Silbersher v. Valeant Pharms. Int'l, Inc.*, 445 F. Supp. 3d 393, 405-06 (N.D. Cal. 2020), a decision now on appeal, which held that the phrase "Federal . . . hearing" in channel (ii) simply includes every Federal hearing, and therefore includes IPRs.

There are a few problems with Defendants' argument. First, the Supreme Court rejected Defendants' characterization of IPRs. In *Return Mail*, the Court characterized PTAB proceedings, including IPRs, as "adversarial, adjudicatory proceedings between the 'person' who petitioned for review and the patent owner." 139 S. Ct. at 1866. In *SAS Institute*, the Court explained that when Congress created IPR, "rather than create (another) agency-led, inquisitorial process for reconsidering patents, Congress opted for a party-directed, adversarial process." 138 S. Ct. at 1355. So even if Defendants' taxonomy of the public disclosure bar is correct, IPRs cannot fall within channel (ii) because they are the type of proceedings that Defendants say fall under channel (i).[8]

Second, as explained above, the statutory text forecloses Defendants' argument that channel (i) includes only adversarial hearings, and channel (ii) includes all non-adversarial administrative hearings. In 2010, Congress deliberately removed the word "administrative" from channel (ii) and placed it only in channel (i), making it clear that if a proceeding qualifies as an "administrative hearing," then it should only trigger the bar if the Government was "a party." Channel (ii) still reaches other hearings, *e.g.*, congressional hearings—but it should not be read so broadly that it sweeps in hearings that Congress addressed in channel (i). *See Allergan*, 2020 WL 7319407, at *25. Moreover, it is wrong to say that channel (i) only includes adversarial hearings; it also includes *ex parte* proceedings. *See ibid*. (explaining that the Patent Act refers to the person seeking a patent repeatedly as a "party," such that patent prosecution could also fall within channel (i)).

Third, to the extent Defendants endorse *Valeant*'s conclusion that *every* Federal hearing falls within channel (ii), they are wrong. That would render channel (i) (which applies only to a specific

[8] Although Defendants rely on *Valeant,* that decision is also at odds with Defendants' proposed construction. The court noted that the PTAB is an "adjudicative body" that conducts IPR "trials" before "patent judges." 445 F. Supp. 3d at 406. That is contrary to Defendants' suggestion that channel (ii) should be read to include "non-adjudicative" "inquisitorial" proceedings. MTD 16.

subset of Federal hearings) entirely superfluous, in violation of cardinal rules of statutory construction. *See Allergan*, 2020 WL 7319407, at *25 (repudiating *Valeant* for this reason).

For similar reasons, Defendants' argument that documents in IPRs are "Federal reports" under channel (ii) is misguided. Documents filed by private parties in IPRs are plainly not "Federal reports," because they are not even prepared or filed by the Government. And an IPR decision is no more a "Federal report" than a judicial decision. Instead, just like judicial decisions, IPR decisions should only trigger the bar if the Government was a party to the case.

If either patent prosecution dockets or IPRs are not within the enumerated channels, then Defendants lose because their argument requires disclosures from both.

2. No Qualifying Public Disclosures Occurred in the News Media

Defendants argue next that triggering disclosures occurred in the "news media," which they say includes "scholarly journals, scientific studies, business articles, competitor websites, and data collected and disseminated by the Government through its websites and databases that disclose the transactions that comprise Relator's allegations." MTD 22. This is so, Defendants argue, because "news media" includes any publicly available website where "information provided is to some extent curated," and has some "indicia of reliability." *Ibid*.

This is wrong. The phrase "the news media" in channel (iii) is not defined, and it takes its ordinary meaning. *See Daubert v. NRA Grp., LLC*, 861 F.3d 382, 389 (3d Cir. 2017) ("When a phrase goes undefined in a statute we give it its ordinary meaning."); *Allergan*, 2020 WL 7319407, at *23 (applying ordinary meaning of "news media" in public disclosure bar); *United States ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*, 2019 WL 3282619, at *15 (C.D. Cal. July 16, 2019) (applying ordinary meaning of "news media" to reject proposition that almost all websites qualify), *rev'd on other grounds* 2021 WL 1233378 (9th Cir. Mar. 31, 2021).

In ordinary parlance, "the news media" refers to professionals who report news to the public. The phrase focuses as much on the content ("news," *i.e.*, important current events) as it does on the speaker (the professional "media," as opposed to individuals or businesses that might

incidentally discuss current events, but not as their focus). For example, everybody would agree that information published in the *New York Times* comes "from the news media" under ordinary parlance. But nobody would describe a restaurant's website, a political scientist's Ph.D. dissertation, a textbook, or PAIR as "the news media," even if those sources discussed current events.[9]

Defendants do not even attempt to argue that triggering disclosures occurred in sources meeting the ordinary meaning of "news media." Instead, they urge the Court to adopt a special, extra-broad interpretation of the phrase, which encompasses every publicly available website that involves any degree of curation and has any indicia of reliability, even if doing so would eviscerate the important changes that Congress made to the FCA in 2010. Defendants propose this radical position because, according to them, the public disclosure bar seeks to prevent people from gathering information on the Internet and making a case out of it. MTD 22.

Defendants' interpretation of the public disclosure bar clashes with the text. Had Congress wanted to make the Internet an enumerated channel for disclosures, it easily could have done so when it amended the statute in 2010, or any time before or after. But Congress did not. Instead, it limited the third channel to "the news media"—and "the news media" plainly does not include many of the sources Defendants cite. Moreover, Defendants' unsupported assertion is contradicted by the legislative history. *See, e.g.,* 145 Cong. Rec. E1547, 1999 WL 495861, at *E1546.; S. Rep. No. 99-345, at 2 & 23-24; S. Rep. No. 110-507, at 5.

To the extent Defendants are arguing that Government websites like PAIR, or the PTAB's equivalent website displaying IPR filings (called PTAB E2E), are "the news media," that argument is wrong for all the reasons that those websites are not "Federal reports"—plus the additional

[9] It is important to read the phrase "the news media" as a whole—and not simply smash together the broadest possible definitions of "news" and "media." *See, e.g.*, *Bostock v. Clayton Cnty., Ga.*, 140 S. Ct. 1731, 1750 (2020) ("[A] statutory phrase ordinarily bears a different meaning than the terms do when viewed individually or literally."); William N. Eskridge Jr., *Interpreting Law* 62 (2016) (a phrase can cover a "dramatically smaller category than either component term"). Indeed, the inclusion of the article "the" before "news media" shows that the phrase refers to a term of art, and not to whoever might fall under the broadest definition of the individual words.

reason that such sources are not part of "the news media" as that term ordinarily is used. *See Allergan*, 2020 WL 7319407, at *24 ("[D]ocket sheets such as PACER and PAIR do not fall within the meaning of the term 'news media' as it is ordinarily used."). This argument also runs into the PACER trap: If Defendants are right that every publicly available, curated website is "news media," then everything on PACER triggers the public disclosure bar, whether the Government is a party to the proceeding or not. Thus, Defendants' interpretation of channel (iii) impermissibly renders channel (i) meaningless. *See ibid.*; *Integra*, 2019 WL 3282619, at *12.

Outside of Government sources, Defendants have not identified any sources that they argue disclose substantially the same "allegations" or "transactions" at issue here. At most, the articles and websites they cite identify bits and pieces that a relator could have used to make parts of his case—but they do not identify the statements or omissions Defendants made to the Government during patent prosecution or drug pricing. Thus, they do not trigger the public disclosure bar. *Cf. Omnicare*, 903 F.3d at 89 (a disclosure cannot merely disclose misconduct at a high level of generality, but must instead disclose the specific fraud alleged in the complaint).

Finally, in deciding whether a particular scholarly journal or niche source of information is the "news media," the Court should use common sense. The bar is designed to prevent parasitic lawsuits. It was not meant to deter relators from combing through dense scientific journals to find studies revealing that pharmaceutical patents are invalid—and combining that insight with a litany of other facts to piece together a fraud case that the Government would never have found.

C. In the Alternative, Silbersher Is an Original Source

Even if there has been a public disclosure in an enumerated forum of all the material elements constituting fraud—which did not occur—Silbersher may still pursue his claims if he is an "original source" possessing "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions."[10] *See* 31 U.S.C. § 3730(e)(4)(B). The question of whether a

[10] The Complaint alleges that Relator provided his information to the Government "before filing this action." ¶ 17. In a typographical error, the Complaint identified this date as June 5, 2019 (which was not "before" this action was commenced). The correct date is June 20, 2017.

relator's knowledge "materially adds to" the publicly disclosed allegations or transactions is a fact issue that should not be resolved on a Rule 12 motion. *Cf. United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101, 104-05 (3d Cir. 2018).

If the Court reaches this question, it should hold that Silbersher is an original source. One of the clearest allegations of fraud—*i.e.*, Defendants misleadingly omitted that Xtandi did not have FDA approval for chemo-naïve patients —does not appear in any of the supposed public disclosures. Silbersher's complaint is the first place this allegation appears. By adding "significant, specific details" to any publicly disclosed information, the Complaint thus materially adds to them. *Moore*, 812 F.3d at 307. The same is true of other allegations of fraud—*e.g.*, ¶ 87(c), (d), (g), (h) (alleging omissions of facts about the ease of using Zytiga versus competitors). More broadly, Silbersher had to piece together the fraud from many different complex, technical sources. This required substantial expertise and is information that is independent of and materially adds to any public disclosure. The Court should thus deny the motion to dismiss.

II. The Complaint Pleads Falsity

Defendants argue that the Complaint does not allege falsity in connection with a claim for payment, MTD 24-25, Federal drug pricing, MTD 26-28, or promissory fraud, MTD 29-33. This obfuscates more than it explains. The Complaint is clear about when, where, and how Defendants deceived the Government: during patent prosecution, and during pricing negotiations. These deceptions caused the Government to pay hundreds of millions of dollars more for Zytiga than it should have, and purchased or reimbursed thousands of Zytiga prescriptions it would otherwise have bought from lower-priced generic competitors, thus tainting all those claims for payment. That is enough to plead that Defendants submitted "false or fraudulent" claims, and used false statements in connection with those claims—and therefore to state claims under the FCA.

A. Defendants' Fraud on the Patent Office Rendered Their Claims for Payment False or Fraudulent

The first theory of FCA liability is that Defendants' original fraud on the Patent Office tainted subsequent claims for payment for the resulting inflated price for Zytiga.

The FCA is broadly construed to apply to claims that are "false or fraudulent," 31 U.S.C. § 3729(a)(1)(A), (B), and not only to claims that are literally false. This includes situations in which an original upstream fraud taints downstream claims. *See United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 904 (9th Cir. 2017); *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1173-74 (9th Cir. 2006); *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 639 (7th Cir. 2016); *Allergan*, 2020 WL 7319407, at *35-40; *United States ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 592 (E.D. Pa. 2014); *see also United States ex rel. Marcus v. Hess*, 317 U.S. 537, 539 & n.1, 542-44 (1943) (explaining that after defendants rigged bids to obtain contracts, the "fraud did not spend itself with the execution of the contract," because its "taint entered into every swollen estimate which was the basic cause for payment" downstream).

The Complaint alleges that Defendants' false and misleading statements to the Patent Office caused it to award the '438 Patent; that the patent was the sole cause of Defendants maintaining their monopoly past December 2016; and that the continued monopoly not only drastically increased the price the Government paid for Zytiga, but it also allowed Defendants to continue selling ten times as many prescriptions of Zytiga for which the Government paid or reimbursed than what Defendants otherwise would have sold. *See supra* pp.1-3. Importantly, the Complaint alleges that none of this was a coincidence. "Approximately 80% of prostate cancer patients in the United States are covered by Medicare," and so the Government is the single largest payer for Zytiga. ¶ 6. Any increase in the price of Zytiga would therefore disproportionately burden the Government. The Complaint thus alleges that "[t]he link between the fraud on the Patent Office and false claims to the government is clear and direct"; indeed, overcharging the Government was the "entire point" of the fraud. ¶ 108. The Complaint thus pleads that the fraud on the Patent Office was both a but-for and proximate cause of the Government overpaying for Zytiga.

The relevant precedents show that this is more than enough. The Ninth Circuit's decision in *Campie* is instructive. There, the relator alleged, among other things, that the defendant deceived the FDA into approving the use of active pharmaceutical ingredients from a facility in China. The district court held that the FCA requires that any false statement "be directed to the government as

part of the reimbursement process" to be actionable. *United States* ex. rel. *Campie v. Gilead Scis., Inc.*, 2015 WL 106255, at *8 (N.D. Cal. 2015). The court thus found that false statements to the FDA were not actionable, because "false certifications, statements, or other fraudulent conduct directed at the FDA during the [drug] approval process do not render subsequent Medicare or Medicaid reimbursement requests made to CMS 'false' under the FCA." *Ibid*.

On the relators' appeal, the Government as *amicus curiae* argued that "even when a claim is not false on its face and does not have a false certification, the claim can nonetheless be 'false or fraudulent' within the meaning of the FCA when it is derived from, and closely connected to, a defendant's antecedent fraud." Gov't Br., 2016 WL 211750, at *12-13. The Government explained that allegations of fraud on the FDA had "a sufficiently close connection" to Government payments because "the effect of [the defendant's] fraud—enabling its drugs to qualify for (among other things) government payment—was not only natural and foreseeable, but was in fact the intended and primary reason for [the defendant's] conduct." *Id*. at *28.

The Ninth Circuit agreed and reversed, explaining that "the False Claims Act imposes no such limitation" requiring frauds to be perpetrated directly against paying agencies. *Campie*, 862 F.3d at 903. "It is not the distinction between the agencies that matters, but rather the connection between the regulatory omissions and the claim for payment." *Ibid*. Thus, when "a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." *Ibid.* (quoting *Hendow*, 461 F.3d at 1174). The "subsequent claims are false because of an original fraud." *Id*. at 902 (quoting *Hendow*, 461 F.3d at 1173).

Similarly, in *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005), the defendant university fraudulently obtained eligibility for educational subsidies by misrepresenting its recruitment practices in its application. That application did not, itself, result in any payments to the university. *Ibid.* Those came later, after the university and its students sought specific grants, loans, or scholarships. *Ibid.* The district court had held that the university's initial fraud was not actionable under the FCA because it did not request "an immediate payment

from the Treasury." *Ibid*. The Seventh Circuit reversed, holding that the fraud was "integral to a causal chain leading to payment," and therefore actionable. *Ibid*.

In *Allergan*, the court held that when the relator alleged that the defendants "misled the Patent Office" to obtain patents "and then used those patents to maintain their monopoly, which then allowed Defendants to charge much higher prices for the drugs than they otherwise could have," defendants' false statements were sufficient to "render their later claims false for the purposes of the FCA." 2020 WL 7319407, at *40.

In *Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA*, 2013 WL 12139832 (C.D. Cal. Apr. 19, 2013), *vacated on other grounds*, 2015 WL 4511573, *vacatur aff'd*, 856 F.3d 696, the plaintiff alleged the defendant used a "fraudulently-obtained patent" to obtain an "exclusive market position" for a drug, charging the United States an "inflated price" for the drug, which the "Government paid." *Id.* at *3. The court held that "[t]hese allegations are sufficient to present an adequately pleaded plausible claim that Aventis submitted, and/or caused to be submitted, false claims to the United States in connection with the alleged scheme." *Ibid*.[11]

This case is indistinguishable from the foregoing authorities, and nearly identical to *Allergan*. Defendants' fraud on the Patent Office enabled them to charge inflated prices for Zytiga to Government payors and to maintain their exclusive market share for Government purchases and reimbursements. Where, as here, the causal connection between Defendants' fraud and subsequent claims for payment is clear, it makes no sense to deny the Government a remedy.

Defendants nevertheless argue that the "upstream fraud" or "promissory fraud" theory applies only to fraudulent attempts to obtain a government contract. MTD 29-31. This is unpersuasive. First, even if Defendants were correct about the law, the Complaint meets this requirement because it alleges that Defendants sold Zytiga to various Government programs pursuant to a Master Agreement ("MA") and a Pharmaceutical Price Agreement ("PPA") that were tainted by fraud.

[11] The *Amphastar* complaint was later dismissed on public disclosure grounds, 2015 WL 4511573, and the Ninth Circuit affirmed that dismissal without commenting on the merits. *Amphastar Pharms., Inc. v. Aventis Pharma SA*, 856 F.3d 696 (9th Cir. 2017). That public disclosure analysis was based on the pre-2010 statute (*see id.* at 702 n.7); it has no relevance here.

¶ 112 (citing 38 U.S.C. § 8126(a)).

More fundamentally, Defendants are wrong about the law. There is no textual basis to limit fraud-in-the-inducement claims to contracts. The statutory definition of a "claim," which includes requests for money or property "*whether under a contract or otherwise*" strongly suggests that such a limitation would be wrong. 31 U.S.C. § 3729(b)(2)(A) (emphasis added). The Supreme Court has likewise refused to adopt "a circumscribed view" of falsity under the FCA. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). Indeed, the Supreme Court has long recognized that Congress's purpose in the FCA was "to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Hess*, 317 U.S. at 544–45. Cases like *Allergan*, *Amphastar*, and *Campie* also reject Defendants' "contracts only" limitation. And they are not alone. *See, e.g.*, *Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 311 (E.D. Pa. 2017) (holding that fraudulent inducement "liability applies not just to government contracts but also to enrollment in government programs"); *United States ex rel. Brown v. Pfizer, Inc.*, 2017 WL 1344365, at *10 (E.D. Pa. Apr. 12, 2017) (fraudulent inducement liability for false statements made to FDA during drug approval process).

The case Defendants cite, *In re Plavix Mktg., Sales Practice and Prods. Liab. Litig.*, 332 F. Supp. 3d 927, 952 (D.N.J. 2017), is distinguishable. There, the court found that the complaint did not allege any "causal connection" between the alleged fraud—misstatements made to a formulary committee that rendered a drug automatically eligible for Medicaid reimbursement—and claims for payment. *Id.* at 953. Here, however, the Complaint alleges that Defendants' fraud on the Patent Office was intended to and did cause the Government to pay more for Zytiga and to purchase or reimburse more prescriptions for Zytiga than it otherwise would have. *See, e.g.*, ¶¶ 108, 124, 132.

Plavix's discussion of cases involving upstream frauds was also incomplete, and the cases it relied upon refute Defendants' argument. Importantly, *Plavix* never cited or discussed *Campie*. Instead, it addressed a single case in which the relator alleged the defendant had defrauded the FDA, but also conceded lack of causation. *See Plavix*, 332 F. Supp. 3d at 956-59 (citing

D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016)). *D'Agostino* does not stand for the proposition that a non-contractual fraud does not give rise to a "fraudulent" claim; it shows that causation is an element of the FCA. *See* 845 F.3d at 9. The Complaint here pleads causation, so *D'Agostino* does not weigh in favor of dismissal.

Defendants also cite *United States ex rel. Promega Corp. v. Hoffman-La Roche Inc*., No. 03-1447-A (E.D. Va. Sept. 29, 2004), for the proposition that the fraud on the Patent Office is too "disconnected" from the inflated invoices to be actionable under the FCA. MTD 31. In *Promega*, the court found "a disconnect between the alleged misrepresentations to the [Patent Office] and the invoices submitted to the Government." Dkt. 128-3, at 5. The relators had attempted to articulate the connection "by claiming that the misrepresentations somehow induced the Government to enter into contracts with the Defendants." *Ibid*. The relators "failed, however, to allege any facts that support such a theory," and so the complaint failed under Rule 9(b). *Ibid*. That holding applies only to the specific facts (or lack thereof) alleged in *Promega*, and no court has ever relied on *Promega* for the broader argument Defendants make here. In any event, the Complaint in this case is manifestly different because it explains how Defendants' fraud caused the payment of false claims.

Promega's "circumscribed" reading of falsity has also been repudiated by well-reasoned authority decided in the 17 years since *Promega* was decided. *See, e.g.*, *Escobar*, 136 S. Ct. at 2002; *Amphastar*, 2013 WL 12139832, at *3 (fraud on the Patent Office taints subsequent claims); *Campie*, 862 F.3d at 903 (fraud on the FDA taints subsequent claims)*; Krahling*, 44 F. Supp. 3d at 592 (same); *Hendow*, 461 F.3d at 1174 (fraud on the Dept. of Education taints subsequent claims). The Court should follow these cases, and not the unpublished, outdated decision in *Promega*, which the issuing court has removed from PACER.

To the extent there is anything to Defendants' argument, it is that in some circumstances, the connection between an antecedent fraud and a later claim for payment may be too attenuated. But that is not a reason to adopt a *per se* rule holding that *only* fraudulent inducement of contracts can give rise to FCA liability. Instead, it is a reason to apply familiar proximate causation standards

connecting antecedent frauds to later claims—which is what courts regularly do in FCA cases. *See, e.g.*, *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3d Cir. 2004) (falsity was established if conduct was "a substantial factor in bringing about" the false claim, and that the claim "was a normal consequence of the situation created by [the fraudulent] scheme"). The Complaint here meets that "substantial factor" test because Defendants' overcharging was a foreseeable—indeed, intended—result of the lies to the Patent Office and to government pricing officials. At a minimum, questions concerning whether the fraud is too attenuated from the injury are factual issues that should not be resolved on a Rule 12 motion. *See United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1040 (C.D. Cal. 2016).

B. Defendants' Pricing Fraud Rendered Their Claims False or Fraudulent

To list Zytiga on the FSS (a precondition for payment under many Government programs), and to set the price that Government payors would pay, Defendants communicated Zytiga's market price to the Government, knowing that would anchor the Government's "fair and reasonable" price inquiry. ¶¶ 106-117. Defendants knew they were using an unlawfully inflated market price to boost the price the Government paid for Zytiga, but they never disclosed it. ¶¶ 110, 117. For the reasons above, this antecedent fraud rendered subsequent claims for payment false.

This misconduct also gives rise to liability under an implied certification theory because the claims for payment implicitly certified that the price was reasonable, when Defendants knew otherwise. In *Escobar*, the relator alleged that claims submitted to Medicaid for counseling services were "false or fraudulent" under the FCA when the claims referred to billing codes corresponding to services such as "family therapy" and job titles such as "Social Worker, Clinical." 136 S. Ct. at 1997. The Supreme Court held that the claims were actionable because the use of the billing codes was "clearly misleading in context. Anyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that" the social worker was qualified and licensed under Massachusetts law. *Id.* at 2000. The social worker was not licensed in Massachusetts, and therefore

the use of the billing codes "without disclosing [the defendant's] many violations of basic staff and licensing requirements . . . constituted misrepresentations" actionable under the FCA. *Id*. at 2000-01. It was irrelevant that the claims for payment did not mention training or qualifications. It also did not matter that licensing requirements were not expressly made conditions of payment: "A statement that misleadingly omits critical facts is a misrepresentation irrespective of whether the other party has expressly signaled the importance of the qualifying information." *Id*. at 2001.

The same is true here. "Defendants' certification that the prices of the drugs they were listing were 'fair and reasonable' misleadingly suggested that they held valid patents on those drugs that allowed them to charge the government higher prices as a result of the monopolies they held on them." *Allergan*, 2020 WL 7319407, at *37. Those representations were prerequisites to claiming reimbursement for Zytiga from certain Government health care programs, such as Medicaid and the Veterans' Administration. *See* ¶ 112. Anybody receiving Defendants' reported "lowest price charged to any commercial customer" would probably—but wrongly—conclude that such price reflected fair market conditions. ¶ 112; *see also* ¶¶ 117, 131. This is especially true because the Government's specific instructions made absolutely clear that Defendants' reported price would serve as the basis for ensuring the price the Government was charged for the medicine remained "fair and reasonable throughout the life of the contract." ¶ 112. And when Defendants sought payment for Zytiga, they knew the Government would only pay a "fair and reasonable" price for it—and they also knew they had tainted the pricing negotiations using a fraudulently inflated market price for Zytiga. ¶¶ 9, 106-17, 124, 131-32. When Defendants then submitted claims for payment, they implicitly reaffirmed they had not inflated the prices by fraud. That affirmation was false and therefore actionable. *See Allergan*, 2020 WL 7319407, at *35-37.

Defendants also say that Silbersher hasn't shown that "pricing agencies ever consider patent validity or status." MTD 29 n.35. That misses the point. What is important is whether Defendants misled the Government into believing that its prices were "fair and reasonable" when they are not. The inflation price made the claims false; the precise reason does not matter.

Defendants also argue that the General Services Administration ("GSA"), through the

Department of Veterans Affairs, conducts a process to determine whether a drug price is "fair and reasonable." MTD 3, 27. All the GSA wants to know, say Defendants, is whether the Government is paying the same prices as commercial payors: So long as a seller accurately reports the prices it charges to commercial payors, it has satisfied all of its regulatory obligations—even if that price is tainted by fraud. *Id.* at 27-28.

That is absurd. Defendants are contending that the Government does not care if it gets ripped off, so long as others also get ripped off. No reasonable payor would take that position. Specifically, no reasonable payor would be indifferent about paying a price for drugs that had been inflated 650% due to fraud. *See* ¶¶ 8, 55, 124-131.

Defendants ignore the *reasons* the Government collects market prices. The Government seeks information about what commercial payors are paying because it assumes that they are paying fair market value. *Cf.* 48 C.F.R. § 15.402(a)(2)(i) (no additional pricing data to establish "fair and reasonable price" is necessary if price is "based on adequate price competition"). But when, as here, a defendant knows it has distorted the market price through a fraudulently obtained patent monopoly, the defendant knows the Government's reasonable assumption is false. In this context, blithely reporting the commercial prices—without disclosing that they have been unlawfully inflated—is the same sort of misleading half-truth the Supreme Court found actionable in *Escobar*.

For similar reasons, Defendants' argument that to state an implied certification claim, the claim must make a specific representation about the goods and services provided, is unpersuasive. MTD 25. In pricing fraud cases generally, a defendant's misrepresentation typically will be that an inflated price is the true price, and such frauds are heartland FCA violations. For example, if a defendant reported inaccurate market prices to the Government to inflate the price the Government would pay for drugs, the FCA would impose liability for subsequent claims. *See, e.g.*, *Garbe*, 824 F.3d at 639; *United States ex rel. Strauser v. Stephen L. LaFrance Holdings, Inc.*, No. 18-CV-673-GKF-FHM, 2019 WL 1086363, at *6 (N.D. Okla. Mar. 7, 2019) (collecting cases). The fact that Defendants here *manipulated* the market price through an upstream fraud—instead of merely *misreporting* it—does not make their conduct less culpable, or the statute less applicable. If

anything, Defendants' conduct here is worse than frauds already found actionable under the FCA.

Moreover, as Defendants themselves acknowledge, courts in this district have rejected the argument that a claim must make specific representations about goods or services to be actionable. *See United States ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 408-09 (D.N.J. 2019) (collecting cases). As the Supreme Court explained in *Escobar*, implied false certification claims are available "at least" where the claims involve specific representations—but "at least" does not mean "only." *Escobar*, 136 S. Ct. at 2001. In any event, the inflated prices for Zytiga *are* representations "about the goods or services provided." *Ibid.*

Defendants also make slippery-slope arguments, wrongly contending that recognizing liability in this case would inappropriately expand the FCA. *See, e.g.*, MTD 29. The FCA is intended "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook County*, 538 U.S. at 129. When, as here, a fraud threatens the public fisc, it falls squarely within the FCA's purview. Second, there is nothing especially novel about Silbersher's claim. A similar case survived a motion to dismiss on the merits in *Amphastar*, and that was years ago. More broadly, the FCA has been used "in various ways to address" "fraudulent schemes contributing to rising drug prices" for years. U.S. Dep't of Justice, Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute (Dec. 2, 2020), https://www.justice.gov/ opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act. Abuse of the patent system is a major contributor to rising drug prices,[12] and the FCA is an ideal tool to curb it. Moreover, recognizing liability here would not lead to liability any time a patent is challenged or found to be invalid—or any time a defendant violates a regulation that may affect drug pricing—because the FCA requires a relator to prove fraud, and not merely a regulatory violation. If a relator

[12] Very recently, the Committee on Oversight and Reform for the House of Representatives issued a report detailing how drug companies—including "Janssen Biotech, Inc., a Johnson & Johnson subsidiary"—have engaged in numerous "anticompetitive pricing practices," including "exploiting the patent system to extend its market monopoly" to waste billions of dollars. https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf. Staff Report, at i.

like Silbersher can demonstrate that drug companies commit fraud that massively inflates the price that the Government pays for medicine, there is no good public policy reason to discourage such suits, contrary to the very purpose of the FCA.

Defendants also ignore the more dangerous slippery-slope risk in the other direction. Defendants' scheme deprived the Government of hundreds of millions of dollars and drove up the cost of medicine for patients with a severe form of cancer. Construing the FCA narrowly to carve out claims like the ones asserted here would give drug manufacturers a green light to continue defrauding the Patent Office, confident that even if the patent is later invalidated, they could reap monopoly profits for at least another 30 months, to the detriment of the public fisc and patients.

C. The Fraudulent Patent Application Is a False Claim Independent of Later Claims for Payment

Independently, the Court should hold that the fraud on the Patent Office was actionable under the FCA even apart from its effect on downstream claims.[13] While most FCA claims are predicated on claims for payment of money, the statute sweeps more broadly. Thus, a "claim" is defined as "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—(i) is presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2)(A). An application for a patent fits this definition of a "claim" because it is a "request" for "property" that is "presented to an officer, employee, or agent of the United States."

Patents are described as "intellectual property," because by their terms, patents "claim" inventions from the public domain for the exclusive benefit of the patentee. As the Supreme Court has explained, patents create a property right in the form of a public franchise. *See Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1373-75 (2018).[14] Indeed, the

[13] This theory of express falsity was briefed in Silbersher's opposition to Defendants' first motion to dismiss that was administratively terminated. Dkt. 89, at 18-20. Defendants do not refute this basis for liability in their motion to dismiss, and the Court should disregard any attempt by Defendants to address it in their reply brief.

[14] The Supreme Court has confirmed repeatedly that patents are property. *See, e.g.*, *Mission Prod. Holdings, Inc. v. Tempnology, LLC*, 139 S. Ct. 1652, 1659 (2019).

Patent Act provides that "[s]ubject to the provisions of this title, patents shall have the attributes of personal property." 35 U.S.C. § 261. Thus, patent owners have the powers associated with property, including the power to exclude others from practicing their inventions.

J&J's fraudulent application for the '438 Patent therefore violated the FCA. It is a false or fraudulent claim, and J&J used false statements in connection with that claim.[15] While the granting of the patent itself did not immediately cause injury to the Government, the Government's subsequent injury from paying substantial overcharges for the medicine was the *intended* purpose, and therefore an integral part of the chain of causation leading to payment. *See, e.g., Campie*, 862 F.3d at 903; *Main*, 426 F.3d at 916. J&J is accordingly liable for civil monetary penalties plus three times the damages sustained "because of [J&J's] act." 31 U.S.C. § 3729(a)(1). That includes the monopoly premium the Government paid for Zytiga after December 2016.

III. The Complaint Pleads Materiality

The FCA's standard for materiality means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court has explained that a matter is material if a reasonable person would attach importance to it, or if the defendant knew or had reason to know that the Government would attach importance to it, "even though a reasonable person would not." *Escobar*, 136 S. Ct. at 2002-03. In

[15] Defendants may cite *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1380 (Fed. Cir. 2000). There, the Federal Circuit held that inequitable conduct on the Patent Office could not establish the predicate offenses of mail fraud and wire fraud for a RICO claim. For those statutes, a claim for fraud requires the defendant to deprive the victim of property the victim possessed, but an unissued patent is not property in the Government's hands. *See id.* The court also rejected the claimant's "attempt to analogize a patent to a franchise," which would have supported a fraud claim. *Id*. For two reasons, *Semiconductor Energy Laboratory* does not control and is not persuasive. First, the mail and wire fraud statutes are different from the FCA. Those laws have long been interpreted narrowly to apply only to schemes to take property in the victim's hands. *See McNally v. United States*, 483 U.S. 350, 360 (1987); *Cleveland v. United States*, 531 U.S. 12, 19-20 (2000). In contrast, the FCA is construed "broadly" to achieve its remedial purpose. *Campie*, 862 F.3d at 899. Congress also broadened the FCA in 2009 by adding the phrase "whether or not the United States has title to the money or property" to the definition of a "claim," confirming that the FCA is not limited to attempts to obtain property in the Government's hands. 31 U.S.C. § 3729(b)(2)(A). The narrow understanding of fraud embodied in the mail and wire fraud statutes is therefore inapplicable to the FCA. *Cf. Loughrin v. United States*, 573 U.S. 351, 360 (2014). Second, the Supreme Court has subsequently rejected the essential holding of *Semiconductor Energy* that a patent is not a franchise. *See Oil States*, 138 S. Ct. at 1373.

some cases—for example those involving liability predicated on alleged regulatory violations—it is maybe unclear whether the violation of some ancillary regulation will have any effect on the Government's payment decisions. In such cases, courts engage in a nuanced inquiry, citing factors cited by the Supreme Court in *Escobar*. Still, the plaintiff wins at the pleading stage if there is a plausible allegation that the fraud was material—even if some factors point in different directions. *See, e.g.*, *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 834-35 (6th Cir. 2018). Here, the Court can skip all that. Materiality is established because the fraud directly inflated the amount the Government paid.

The Complaint pleads materiality in two ways. First, it pleads that the fraud on the Patent Office caused the Government to issue the '438 Patent. ¶¶ 63-90. That allegation is certainly plausible, because the Patent Office previously rejected the application for obviousness, reversing course only after Defendants misrepresented that Zytiga's commercial success was attributable to the claimed invention. ¶¶ 64-65, 75-90. The Complaint alleges the Patent Office "issued the '438 Patent" "[b]ased on Defendants' false and misleading representations and reliance thereon." ¶ 90. That is sufficient as to the theory that the fraud on the Patent Office was itself a false claim.

Second, the Complaint pleads that Defendants' fraud was material to the Government's payment decisions. ¶¶ 120-132. A reasonable payor would not want to pay inflated prices for drugs—and the Government behaves reasonably in this regard by encouraging generic competition, and by buying cheaper drugs when they are available. ¶¶ 44-47, 57, 109. The Complaint pleads representative examples of when the Government has taken enforcement actions to ensure adequate price competition from generic manufacturers. ¶¶ 127-130; *see also F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 145 (2013). The Government has also successfully pursued claims based on fraud on the Patent Office that excluded generic competition.[16] Thus, there is no doubt that if Defendants had not fraudulently excluded generics from the market, the Government would

[16] *See*, *e.g.*, *F.T.C. v. Cephalon, Inc.*, 36 F. Supp. 3d 527, 534 (E.D. Pa. 2014) ("The conclusion that Cephalon committed fraud on the Patent Office is significant because patents procured by fraud do not, as a general rule, provide a defense under the antitrust laws").

have bought abiraterone acetate from those companies at lower prices instead of from Defendants.

More broadly, the price of drugs goes to "the essence of the bargain" between drug manufacturers and the Government. Price is a quintessential material contract term. J. D. Calamari & J.M. Perillo, *The Law of Contracts*, § 2-13, at 43-44 & n. 17 (2d ed. 1977); *see Unihan Corp. v. Max Group Corp.*, 2011 WL 6814044, at *7 (C.D. Cal. 2011) (price of a product is a material contractual term). When a fraud causes the Government to pay more than it should, materiality is met. *See, e.g.*, *Allergan*, 2020 WL 7319407, at *41; *Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1105 (11th Cir. 2020); *Garbe*, 824 F.3d at 639; *United States ex rel. Campbell v. KIC Dev., LLC*, 2019 WL 6884485, at *12 (W.D. Tex. Dec. 10, 2019); *Strauser*, 2019 WL 1086363, at *14 ; *United States ex rel. Stepe v. RS Compounding LLC*, 325 F.R.D. 699, 708 (M.D. Fla. 2017); *United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 177 F. Supp. 3d 712, 715 (D. Mass. 2016); *United States ex rel. Shemesh v. CA, Inc.*, 89 F. Supp. 3d 36, 52 (D.D.C. 2015); *United States ex rel. Ubl v. IIF Data Sols.*, 2007 WL 2220586, at *4 (E.D. Va. Aug. 1, 2007).

Defendants argue that an effect on price cannot create materiality *per se*—but the cases cited above say otherwise, and none of Defendants' cases on this point are about pricing. Any effect on price meets the plain text of the statute and the Supreme Court's discussion in *Escobar*. Even if price impact were not entirely conclusive, it is a strong factor in Silbersher's favor—and therefore enough, at the pleading stage, to take this case forward.

Defendants also argue that the Government's continued payments for Zytiga disprove materiality. MTD 33-35. But continued payments do not help Defendants. First, even if the Government continues to pay claims with knowledge of a violation, that is not dispositive. *See Prather*, 892 F.3d at 834. Second, there is no allegation that any paying agency had actual knowledge of Defendants' fraud at the time payments were made. *Ibid.* ("Without actual knowledge of the alleged non-compliance, the government's response to the claims submitted by the defendants . . . has no bearing on the materiality analysis."); *United States ex rel. Escobar v. Universal Health Servs., Inc.,* 842 F.3d 103, 112 (1st Cir. 2016) ("[M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual

noncompliance."); *United States ex. rel. Armstrong v. Andover Subacute & Rehab Ctr. Servs. One, Inc.*, 2019 WL 4686963, at *6 n.16 (D.N.J. Sept. 26, 2019). Third, even when the Government pays with knowledge of a violation, it may have good reasons unrelated to materiality to do so (*i.e.*, to ensure cancer patients get treated). *See Campie*, 862 F.3d at 906.

Because it is at least plausible that Defendants' fraud—which the Complaint alleges had a massive effect on the price the Government paid for Zytiga—was material to the Government's payment decisions, Defendants' materiality arguments should be rejected.[17]

IV. Defendants' Inequitable Conduct Argument Is Meritless

Defendants argue the Complaint fails to plead "fraud on the PTO." MTD 35. The gist of this argument is that any allegation of fraud on the Patent Office must meet the heightened standard for "inequitable conduct." Inequitable conduct, in turn, is a judge-made affirmative defense to patent infringement that has been described as "the 'atomic bomb' of patent law" because it "render[s] the entire patent," as opposed to individual claims, "unenforceable"; and it can "spread from a single patent to render unenforceable other related patents and applications in the same technology family," endangering "a substantial portion of a company's patent portfolio." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (citation omitted). These and other concerns led the Federal Circuit to "tighten[] the standards for finding both intent and materiality" in inequitable conduct defenses. *Id*. at 1290.

These standards are inapplicable to FCA claims because the FCA has its own statutory scienter and materiality rules. The FCA's intent standard can be satisfied by intentional conduct or by recklessness and requires "no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). The FCA eschews but-for causation in favor of materiality. 31 U.S.C. § 3729(b)(4). It is also well-established that misleading omissions are actionable under the FCA. *See, e.g., Escobar*, 136 S. Ct. at 1999. Finally, the policy reasons underlying *Therasense* do not apply to FCA claims.

[17] The Texas Attorney General has requested Relator to inform the Court that Silbersher is not required to plead the submission of false claims under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§ 36.002(1)-(13), for the majority of unlawful acts, or that an unlawful act was material to payment, to satisfy Rule 9(b). *See* TEX. HUM. RES. CODE § 36.001(5-a).

In an effort to shoehorn their legal standard into the FCA, Defendants argue that the violation in this case is predicated on a violation of 37 C.F.R. § 1.56 (the Patent Office's standard of candor and good faith), and that FCA cases predicated on violations of other laws must prove those violations, including any attendant scienter requirements. MTD 35-36. That mischaracterizes Silbersher's claims, which do not rely on 37 C.F.R. § 1.56 as an "underlying violation" in the same way that a Stark Act violation may be the basis for an FCA case. The FCA applies by its own force when a defendant lies to the Government to obtain money or property—and the Complaint is predicated on violations of those statutory provisions. *See* 31 U.S.C. § 3729(a)(1)(A), (B). Whether a separate regulation also prohibits lying to the Patent Office does not displace that liability.

Defendants' sole justification to the contrary is a one-sentence policy argument that if the inequitable conduct standard does not apply, relators "could circumvent patent protections by seeking to hold patent owners liable for fraud when no such liability would otherwise exist." MTD 36. Defendants' argument fails because Congress legislated in this area, and courts have no power to ignore the words Congress used simply because those words displace a previously existing judge-made standard. Moreover, the FCA seeks a different remedy than the inequitable conduct defense. It is entirely sensible that Congress would adopt a looser liability standard for claims to protect the public fisc than courts would adopt for affirmative defenses in private patent disputes. Indeed, that is why the FCA's fraud standard is looser than common law fraud (which requires specific intent and reliance): Congress gave the Government special protection.

Even considering the matter through the lens of inequitable conduct, Defendants' argument is wrong. The Complaint alleges with particularity that J&J *intentionally* misstated Zytiga's commercial success and misleadingly omitted material information *because* J&J knew that such disclosures would scuttle their application. ¶¶ 82-88. Such allegations easily demonstrate a "deliberately planned and carefully executed scheme" to fraudulently obtain a patent for the purpose of excluding competitors and artificially raising or maintaining prices for Zytiga. *See Therasense*, 649 F.3d at 1290 (internal citations omitted); *see also Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 2005 WL 8156817, at *3 (C.D. Cal. May 2, 2005) (false statements

concerning commercial success was "clear and convincing evidence of inequitable conduct").

Under 37 C.F.R. § 1.56, "intentional misconduct" is a bar to patentability. At the pleading stage, J&J's assertions that they did not act intentionally cannot be credited because the Complaint's allegations of intentional misconduct are plausible in light of previous rejections by the Patent Office of J&J's "commercial success" submissions. *See* ¶ 86. And these sort of scienter questions are typically matters for a trier of fact, even in inequitable conduct cases (and certainly in FCA cases). *See, e.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, 90 F. Supp. 2d 522, 528 (D.N.J. 2000) ("[A] fact finder may infer deceptive intent when a patent applicant withholds potentially pertinent information and makes arguments for patentability which could not have been made had the information been disclosed."); *Skedco, Inc. v. Strategic Operations, Inc.*, 287 F. Supp. 3d 1100, 1149-50 (D. Or. 2018) (denying summary judgment against inequitable conduct).

Although not necessary, Silbersher also pleads "but-for" materiality as a matter of patent law. For withheld information to be deemed material for inequitable conduct, the information must not be cumulative of information on record with the Patent Office, and it must either establish a *prima facie* case of unpatentability of a claim; or refute, or be inconsistent with, a position asserted to obtain a patent. *See Purdue Pharma, L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006) (quoting 37 C.F.R. § 1.56(a)). The Complaint alleges that the Patent Office had rejected numerous times the application for the '438 Patent, ¶ 75; the patent examiner specifically instructed Defendants to provide relative market share comparisons if they wished to demonstrate "commercial success" necessary to have the patent issued, ¶ 80; and Defendants' misleading statements in response were the "but-for" cause for the issuance of the patent, ¶¶ 85-86.

Moreover, Defendants' fraud is not simply a garden-variety instance of withholding prior art, but rather affirmatively lying to the Patent Office by suggesting that Zytiga's commercial success was due to its co-administration with prednisone. Misrepresented information is necessarily material if a court invalidates a patent based on such information. *Therasense*, 649 F.3d at 1292. Here, this Court, the PTAB, and the Federal Circuit considered information identified in the Complaint, such as the blocking nature of the '213 patent, as sufficient to overcome Defendants'

commercial success argument. *See, e.g.*, *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp.3d 352, 386-87 (D.N.J. 2018); *Wockhardt Bio AG v. Janssen Oncology, Inc.,* 2018 WL 456328, at *16 (P.T.A.B. Jan. 17, 2018); *BTG*, 923 F.3d at 1076.

Finally, Defendants say that inequitable conduct imposes the duty of "candor and good faith" on individuals filing documents with the Patent Office, and not on corporations. MTD 33. Defendants argue that the Complaint does not plead specific individuals who prosecuted the '438 Patent on behalf of J&J had "specific intent"[18] to deceive. MTD 33-34 (citing inequitable conduct cases). This simply ignores the detailed pleading in ¶¶ 63 through 82 of the Complaint.

In any event, J&J is chargeable with the fraud. J&J, as the real party in interest to the '438 Patent, obtained it through fraud. ¶¶ 82-89. It did so through filings by its attorneys, employees, and agents, all of whom had obligations of candor and good faith when prosecuting the patent on behalf of their principals. *See, e.g.*, ¶¶ 69-71, 82-89. Defendants cannot escape liability by hiding behind their agents. *See Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("If an individual who is substantively involved in the preparation or prosecution of an application fails to comply with his duty of candor, then that individual's misconduct is chargeable to the applicant for the patent"); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 & n.1 (Fed. Cir. 1995); *Competitive Techs. v. Fujitsu Ltd.*, 286 F. Supp. 2d 1118, 1149 (N.D. Cal. 2003).

More generally, outside of patent infringement actions, principals are liable for the fraud committed by their agents. *See Am. Soc'y of Mech. Eng'rs v. Hydrolevel Corp*., 456 U.S. 556, 566 (1982). Business entities such as Defendants may only act through natural persons. The law therefore charges them with the combined knowledge that comes to them through their employees or agents. *See, e.g.*, *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 745 n.9 (10th Cir. 2018); *Frank v. Dana Corp.*, 646 F.3d 954, 963 (6th Cir. 2011).

V. BTG Participated in the Fraud

As this Court previously found, and as the Complaint alleges, BTG is a co-owner of the '438

[18] Contrary to Defendants' argument, the FCA makes clear that intent may be pleaded generally, and the statute "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B).

Patent. ¶ 91; *BTG*, 352 F. Supp. 3d at 358. BTG argues that the '438 Patent was prosecuted by J&J, but the fraud alleged is not limited to obtaining the patent. The scheme also encompasses asserting the patent against generic competitors to unlawfully inflate the prices the Government paid for Zytiga, and also to take away the Government's ability to choose less-expensive generics. *See* ¶¶ 92-132. BTG was involved in all of that subsequent misconduct and therefore is jointly and severally liable. *See, e.g.*, *Mortgs., Inc. v. United States Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991); *United States v. Bourseau*, 2006 WL 2961105, at *13 (S.D. Cal. Sept. 29, 2006). BTG was also the owner of the '213 blocking patent and had licensed it to J&J's predecessor-in-interest; a reasonable juror could find that it had the requisite knowledge that it was enforcing a fraudulent patent that had failed to disclose the '213 patent in the submissions relating to commercial success.

Analogizing to inequitable conduct cases (from which this case is *a fortiori*), BTG would be liable even if it had no role in the fraud because, in cases involving allegations of inequitable conduct, the consequences of patent fraud do not disappear even when a patent is transferred to an innocent third-party. Instead, the Federal Circuit has confirmed that a patent-plaintiff is liable for asserting patents acquired from a third party that committed inequitable conduct—even though there was no direct evidence that the plaintiff previously knew about the misconduct—because the plaintiff "should have known" that the patents "were unenforceable." *See In re Rembrandt Techs. LP Patent Litig.*, 899 F.3d 1254, 1272 (Fed. Cir. 2018).

Put another way: Fraud on the Patent Office cannot be laundered out by transferring the interest in the fraudulent patents to a third party such as BTG. As a current owner of the '438 Patent, BTG is liable for how the patents were obtained and then used to exploit the Government.

CONCLUSION

The Motion to Dismiss should be denied in its entirety. In the alternative, the Court should permit Silbersher to amend his pleadings should there be any deficiency.

Dated: May 20, 2021

LITE DEPALMA GREENBERG & AFANADOR, LLC

/s/ Bruce D. Greenberg
Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
bgreenberg@litedepalma.com

HERRERA KENNEDY LLP
Nicomedes Sy Herrera (*pro hac vice*)
Laura E. Seidl (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com
LSeidl@HerreraKennedy.com

GOLDSTEIN & RUSSELL, P.C.
Tejinder Singh (*pro hac vice*)
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636
TSingh@goldsteinrussell.com

Attorneys for Plaintiff-Relator Zachary Silbersher